IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HARVINDER S. SANDHU, M.D. and KYPHON, INC.,	)	
Plaintiffs,	)	Civil Action No. 05-2863-MI V
v.	)	
MEDTRONIC SOFAMOR DANEK, INC., MEDTRONIC SOFAMOR DANEK USA, INC. and SDGI HOLDINGS, INC.,	)	
Defendants.	)	

DEFENDANTS' AMENDED ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT AND COUNTERCLAIMS AGAINST KYPHON INC. AND HARVINDER S. SANDHU, M.D.

Defendants Medtronic Sofamor Danek Inc. ("MSD Inc."), Medtronic Sofamor Danek U.S.A. Inc. ("MSD USA"), and SDGI Holdings Inc. ("SDGI") (collectively, "Defendants" or "Medtronic") hereby submit (1) their Amended Answer to the First Amended Complaint filed by Plaintiffs Harvinder S. Sandhu, M.D. ("Dr. Sandhu") and Kyphon Inc. ("Kyphon") (collectively, "Plaintiffs"), and (2) the Amended Counterclaims of MSD Inc., MSD USA, and SDGI against Kyphon Inc. and Harvinder S. Sandhu, M.D. (collectively the "Amended Answer and Counterclaims").

ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Except as expressly admitted hereinafter, Defendants deny each allegation contained in the First Amended Complaint.

INTRODUCTION

1. Defendants admit this dispute involves patents related to treatment of the spine. Defendants admit that U.S. and foreign patent applications related to the treatment of the spine have been filed on behalf of defendant SDGI, one of which has issued as U.S. Patent No. 6,676,665 (the "'665 Patent"). Defendants also admit that Dr. Sandhu is not named as an inventor on those patent applications or the '665 Patent. Defendants deny that Dr. Sandhu ought to have been named as an inventor on the '665 patent or the pending patent applications. Defendants deny the remaining allegations of this paragraph.

THE PARTIES

2. Defendants admit that Dr. Sandhu is a spinal surgeon from New York. Defendants deny that Dr. Sandhu licensed his alleged spinal inventions exclusively to Kyphon. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, deny them.

4. Defendants admit that "kyphoplasty" refers to a technique of inflating a balloon in a vertebral body and then injecting bone cement. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

5. Defendants admit that Kyphon holds certain patents, the contents of such patents are as set forth in the patents, subject to such further interpretation as is permitted by law. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

6. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, deny them.

7. Admitted.

8. Admitted.

9. Admitted.

10. Defendants admit that SDGI is incorporated under the laws of the State of Delaware. Defendants deny that SDGI's principal place of business is in Memphis, Tennessee.

11. Defendants admit that Sofamor Danek Group Inc. is a predecessor of MSD Inc. and that on January 27, 1999, MSD Inc. became a wholly owned subsidiary of Medtronic Inc.

12. Defendants admit that defendant SDGI is a wholly owned subsidiary of MSD Inc. that holds some of the intellectual property covering MSD Inc.'s products. Defendants also admit that MSD USA is a wholly owned subsidiary of MSD Inc. that performs functions related to the sale of MSD Inc.'s products. Defendants further admit that MSD Inc. performs, inter alia, functions related to product development, manufacturing, and marketing, and that it controls the prosecution and enforcement of patents related to its products. Defendants deny the remaining allegations of this paragraph.

JURISDICTION AND VENUE

13. Defendants admit that this Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331 and that it has jurisdiction pursuant to 28 U.S.C. § 1338 over Plaintiffs' claims for correction of inventorship related to issued patents. Defendants deny that this Court has jurisdiction to adjudicate any claims related to pending patent applications. Defendants admit that this Court has discretion pursuant to 28 U.S.C. § 1367 to exercise supplemental jurisdiction.

14. Admitted.

15. Defendants admit that for all claims other than Plaintiffs' patent infringement claims venue is proper in this Court pursuant to 28 U.S.C. § 1391. Defendants deny that this is the proper venue for Plaintiffs' patent infringement claims. Defendants deny the remaining allegations of this paragraph.

ALLEGED FACTS

16. Defendants admit that Dr. Sandhu entered into a consulting agreement with Sofamor Danek Group Inc., on March 10, 1998. The terms of the consulting agreement are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Dr. Sandhu also entered into other agreements with MSD Inc., MSD USA, and their predecessors, including a Confidentiality Agreement that was effective on January 2, 1996; a Mutual Confidentiality Agreement that was effective on March 18, 1999; a Confidentiality Agreement that Dr. Sandhu signed on January 22, 2000; a Consulting Agreement that Dr. Sandhu signed on March 16, 2001; a Consulting Agreement that Dr. Sandhu signed on April 26, 2002; and an Exclusive Personal Services Agreement that Dr. Sandhu signed on May 25, 2003.

17. Defendants deny that Dr. Sandhu approached Michael Sherman regarding kyphoplasty inventions that used an expandable, directional bone tamp to treat vertebral compression fractures by compacting bone inside a vertebra and reducing the fractures. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

18. Defendants admit that Dr. Sandhu entered into an agreement with Sofamor Danek Group Inc. on March 18, 1999, entitled "Mutual Confidentiality Agreement" (the "1999 Agreement"). Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

19. Defendants admit that Dr. Sandhu provided Sofamor Danek Group Inc. with a disclosure. The terms of the 1999 Agreement are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

20. Defendants admit that Dr. Sandhu provided Sofamor Danek Group Inc. with a disclosure. The terms of the 1999 Agreement are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Defendants admit that U.S. Application No. 09/928,949 (the "'949 application"), that issued as the '665 patent, entitled "Surgical Instrumentation and Method for Treatment of the Spine," and claims priority to a provisional application filed on August 11, 2000, was assigned by its named inventors to SDGI. Defendants also admit that U.S. Application Nos. 10/778,650 (the "'650 application"), 10/756,970 (the "'970 application"), and PCT Application No. WO 0213700A2 (the "'700 application") were assigned to SDGI. Defendants admit that SDGI is the owner of the '665 patent and the '970, '650, and '700 applications. Defendants also admit that Dr. Sandhu is not named as an inventor on the '665 patent and the '970, '650, and '700 applications, or any foreign counterparts. The inventions in the '665 patent and the '970, '650, and '700 applications were made by their named inventors.

21. Defendants admit that in 2002, Michael DeMane offered Dr. Sandhu the opportunity to work on a project to develop treatments for vertebral compression fractures, including the development of a cement injector system for that project. Defendants admit that the project became known inside Medtronic as the Equestra project.

22. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, because the allegations are vague with respect to the timing and source of the purported communications, and, therefore, deny them.

23. Defendants admit that Dr. Sandhu attended a lab at the MERI center in December 2002 to test on cadavers, prototypes developed by MSD USA consultants and engineers. Defendants admit that Dr. Kevin Foley and at least one engineer who reported to Mike Sherman were at the lab. Defendants admit that one device tested at the lab was a device that had been developed by Dr. Foley, and another device tested at the lab was a device developed by Dr. Pagano. Defendants admit that Dr. Sandhu traveled to Memphis to meet and consult with MSD USA. Defendants deny the remaining allegations of this paragraph.

24. Defendants admit that the Equestra team included, among others, Mr. Sherman and Dr. Foley. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, because the allegations are vague with respect to the timing and source of the purported inquiries, and, therefore, deny them.

25. Defendants admit that during 2003 and 2004, Dr. Sandhu provided assistance or feedback to MSD USA personnel in connection with the Equestra project, including in the development of a cement injector system. Defendants deny that Dr. Sandhu was without a contractual agreement with Medtronic governing Dr. Sandhu's involvement in the Equestra Project during 2003 and 2004. Defendants deny the remaining allegations of this paragraph.

26. Defendants admit that in 2004, Mr. DeMane and Mr. Wehrly joined Dr. Sandhu for dinner in Memphis. Defendants also admit that during this dinner, Dr. Sandhu mentioned that he had discussed fracture repair with Medtronic years before. Defendants deny the remaining allegations of this paragraph.

27. Defendants admit that Dr. Sandhu met Mr. DeMane at a spine meeting in 2004, and that they may have discussed Dr. Sandhu's disclosure at that time. Defendants lack specific information to verify the date and location of such a meeting at this time. Defendants deny that no one from Medtronic advised Dr. Sandhu that Medtronic had already filed for patents allegedly related to the treatment of spinal disorders. By 2004, Dr. Sandhu had already been informed that a patent had been filed. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, deny them.

28. Defendants admit that in early 2005, Billy Albans, an Equestra product manager, communicated with Dr. Sandhu to confirm the accuracy of certain methods described in a draft Equestra brochure. Defendants admit that the sketches in the brochure showed a device based on the device conceived and developed by Dr. Pagano. Defendants deny the remaining allegations of this paragraph.

29. Defendants admit that Mr. Albans and Dr. Sandhu later had a telephone conversation to discuss the accuracy of medical steps discussed in the Equestra brochure previously provided to Dr. Sandhu. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations that Mr. Albans reviewed the history of the Equestra project, because the phrase "history of the Equestra project" is vague and, therefore, Defendants deny them. Defendants deny that Mr. Albans reviewed whether the project had been supervised by Mr. Sherman. Defendants deny the remaining allegations of this paragraph.

30. Defendants admit that in March 2005, Dr. Sandhu met with Mr. Wehrly and Todd Sheldon at Dr. Sandhu's request and that the meeting was held in Mr. Wehrly's office. Defendants deny the remaining allegations of this paragraph.

31. Defendants admit that Mr. Sheldon advised Dr. Sandhu to seek his own legal counsel. Defendants deny the remaining allegations of this paragraph.

32. Denied.

33. Defendants admit that SDGI has not assigned the '665 patent and the '970, '650, and '700 patent applications to Dr. Sandhu or named Dr. Sandhu as an inventor. Defendants deny the remaining allegations of this paragraph.

34. Defendants admit that Medtronic received FDA approval for manual surgical instruments to be offered under the trade name Equestra Fluid Delivery System to provide physicians with a percutaneous means of delivering legally cleared bone cement to the surgical site in procedures. Defendants admit that physicians have used surgical instruments provided by Medtronic to deliver legally cleared bone cement to the surgical site in orthopedic procedures in the United States. Defendants deny that they have encouraged anyone to perform a Kyphoplasty. Defendants deny the remaining allegations of this paragraph.

35. Defendants admit that Medtronic is evaluating a product for the treatment of spinal disorders. Defendants deny the remaining allegations of this paragraph.

Count I: Correction of Inventorship on Medtronic's Issued Patent

36. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

37. Denied.

38. Admitted.

39. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, deny them.

40. Denied.

Count II: Correction of Inventorship on Medtronic's Pending Patent Applications

41. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

42. Denied.

43. Admitted.

44. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, deny them.

45. Denied.

Count III: Theft of Trade Secrets

46. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

47. In view of the vagueness of the first sentence of this paragraph with respect to time and scope, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this sentence and, therefore, deny them. The allegations in the second sentence of this paragraph are denied

48. On information and belief, Defendants deny the allegations in this paragraph.

49. Defendants admit that Sofamor Danek Group Inc. and Dr. Sandhu entered into an agreement entitled "Mutual Confidentiality Agreement" on March 18, 1999, and that Dr. Sandhu disclosed information to Sofamor Danek Group. Defendants deny the remaining allegations of this paragraph.

50. Denied.

51. Denied.

52. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and, therefore, deny them.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

Count IV: Fraudulent Concealment and Misrepresentation

57. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

Count V

[RESERVED]

Count VI: Breach of Contract

64. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

65. Defendants admit that on March 18, 1999, Dr. Sandhu and Sofamor Danek Group, Inc. entered into an agreement entitled "Mutual Confidentiality Agreement." The terms of the 1999 Agreement are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Defendants deny the remaining allegations of this paragraph.

66. The terms of the 1999 Agreement are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Defendants deny the remaining allegations of this paragraph.

67. Defendants admit that Dr. Sandhu provided Sofamor Danek Group, Inc. with a disclosure pursuant to the 1999 Agreement. Defendants deny the remaining allegations of this paragraph.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

Count VII: Breach of Implied Covenant of Good Faith and Fair Dealing

73. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 and 66-74 above, as though fully set forth herein.

74. Defendants admit that it had contractual Agreements with Dr. Sandhu. The terms of the agreements are as set forth in the written agreement, subject to such further interpretation as is permitted by law. Defendants deny the remaining allegations of this paragraph.

75. Denied.

67. Denied.

77. Denied.

Count VIII: Deceptive Acts and Violations of the Tennessee Consumer Protection Act

78. Defendants repeat and incorporate by reference the answers to paragraphs 1-35 above, as though fully set forth herein.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

COUNT IX: Infringement of U.S. Patent No. 4,969,888

83. Defendants repeat and incorporate by reference the answers to paragraphs 1-15 and 34-35 above, as though fully set forth herein.

84. Defendants admit that U.S. Patent No. 4,969,888 (the "'888 patent") issued on November 13, 1990. Defendants deny that the '888 patent was duly and legally issued. Defendants lack sufficient information to admit or deny the remaining allegations of this paragraph and therefore deny them.

85. Defendants admit that a copy of the '888 patent appears to be attached to the First Amended Complaint as Exhibit B. Defendants deny the remaining allegations of this paragraph.

86. Defendants lack sufficient information to admit or deny the allegations of this paragraph and therefore deny them.

87. Denied.

88. Denied.

89. Denied.

COUNT X: Infringement of U.S. Patent No. 5,108,404

90. Defendants repeat and incorporate by reference the answers to paragraphs 1-15 and 34-35 above, as though fully set forth herein.

91. Defendants admit that U.S. Patent No. 5,108,404 (the "'404 patent") issued on April 28, 1992. Defendants deny that the '404 patent was duly and legally issued. Defendants

lack sufficient information to admit or deny the remaining allegations of this paragraph and therefore deny them.

92. Defendants admit that a copy of the '404 patent appears to be attached to the First Amended Complaint as Exhibit C. Defendants deny the remaining allegations of this paragraph.

93. Defendants lack sufficient information to admit or deny the allegations of this paragraph and therefore deny them.

94. Denied.

95. Denied.

96. Denied.

COUNT XI: Infringement of U.S. Patent No. 6,235,043 B1

97. Defendants repeat and incorporate by reference the answers to paragraphs 1-15 and 34-35 above, as though fully set forth herein.

98. Defendants admit that U.S. Patent No. 6,235,043 B1 (the "'043 patent") issued on May 22, 2001. Defendants deny that the '043 patent was duly and legally issued. Defendants lack sufficient information to admit or deny the remaining allegations of this paragraph and therefore deny them.

99. Defendants admit that a copy of the '043 patent appears to be attached to the First Amended Complaint as Exhibit D. Defendants deny the remaining allegations of this paragraph.

100. Defendants lack sufficient information to admit or deny the allegations of this paragraph and therefore deny them.

101. Denied.

102. Denied.

COUNT XII: Infringement of U.S. Patent No. 6,440,138 B1

103. Defendants repeat and incorporate by reference the answers to paragraphs 1-15 and 34-35 above, as though fully set forth herein.

104. Defendants admit that U.S. Patent No. 6,440,138 B1 (the "'138 patent") issued on August 27, 2002. Defendants deny that the '138 patent was duly and legally issued. Defendants lack sufficient information to admit or deny the remaining allegations of this paragraph and therefore deny them.

105. Defendants admit that a copy of the '138 patent appears to be attached to the First Amended Complaint as Exhibit E. Defendants deny the remaining allegations of this paragraph.

106. Defendants lack sufficient information to admit or deny the allegations of this paragraph and therefore deny them.

107. Denied.

108. Denied.

COUNT XIII: Infringement of U.S. Patent No. 6,863,672 B2

109. Defendants repeat and incorporate by reference the answers to paragraphs 1-15 and 34-35 above, as though fully set forth herein.

110. Defendants admit that U.S. Patent No. 6,863,672 B2 (the "'672 patent") issued on March 8, 2005. Defendants deny that the '672 patent was duly and legally issued. Defendants lack sufficient information to admit or deny the remaining allegations of this paragraph and therefore deny them.

111. Defendants admit that a copy of the '672 patent appears to be attached to the First Amended Complaint as Exhibit F. Defendants deny the remaining allegations of this paragraph.

112. Defendants lack sufficient information to admit or deny the allegations of this paragraph and therefore deny them.

113. Denied.

114. Denied.

PRAYER FOR RELIEF

Defendants deny any allegations asserted against them in the prayer for relief, and deny that Plaintiffs are entitled to the relief sought in their First Amended Complaint.

AFFIRMATIVE DEFENSES

Without assuming any burden other than that imposed by operation of law or admitting that they bear the burden of proof with respect to any of the following, Defendants allege as follows:

First Defense

(Failure to State a Claim)

The First Amended Complaint, and each of its purported claims for relief, fails to state a claim upon which the relief sought, or any relief, may be granted.

Second Defense

(Independent Inventorship)

The information Dr. Sandhu alleges Defendants have misappropriated from Dr. Sandhu was developed through the independent efforts of one or more third parties who are not in breach of any agreement with Dr. Sandhu.

Third Defense

(Laches, Waiver, Acquiescence, Estoppel and Unclean Hands)

Plaintiffs' claims against Defendants and their prayers for relief may be barred or limited by the equitable doctrines of laches, waiver, acquiescence, estoppel and unclean hands.

Fourth Defense

(Causation)

To the extent Plaintiffs have suffered damages as alleged in the First Amended Complaint, which Defendants deny, such damages were not caused by Defendants, but by the acts or omissions of Plaintiffs or others.

Fifth Defense

(No Punitive Damages)

The actions alleged in the First Amended Complaint were at all times reasonable, privileged and justified, and were conducted in good faith, without fraud, oppression, intent, recklessness or malice, thereby precluding any and all claims for punitive or exemplary damages. Moreover, the claim for punitive damages is barred by, or limited by, Defendants' rights under United States Constitution and Tennessee Constitutions and Tennessee common law.

Sixth Defense

(Failure to Mitigate Damages)

Plaintiffs have had and continue to have the ability and opportunities to mitigate the damages alleged in their First Amended Complaint and have failed to act reasonably to mitigate such damages.

Seventh Defense

(No Misappropriation)

Defendants did not disclose, use, or misappropriate any alleged "trade secret" belonging to Dr. Sandhu.

Eighth Defense

(Trade Secrets Claim Displaced by Contract)

Pursuant to the March 18, 1999, Agreement, any disclosed information ceased to be confidential after five years or by any means described in paragraph 6 of the Agreement.

Ninth Defense

(Statute of Limitation or Repose)

Plaintiffs' claims are barred and their recovery of damages is precluded, in whole or in part, by the applicable statute of limitation or repose.

Tenth Defense

(No False Representation of Material Fact)

Defendants made no false representation of material fact to Dr. Sandhu upon which a fraud claim may be based and made no false representations of material fact to any other party with the intent that it be communicated to Dr. Sandhu.

Eleventh Defense

(No Intent to Induce Reliance by Dr. Sandhu or to Defraud Dr. Sandhu)

Defendants (1) made no false representation of material fact to Dr. Sandhu; (2) made no false representation of material fact to any other party with the intent that it be communicated to Dr. Sandhu; (3) did not make any such representations with the intent to defraud Dr. Sandhu; and (4) did not make any such representations to induce Dr. Sandhu to act upon them.

Twelfth Defense

(Lack of Reliance and Unjustifiable Reliance)

Dr. Sandhu did not, in fact, act or fail to act to his detriment in reliance on any allegedly fraudulent representation or concealment attributable to Defendants, and any such purported reliance by Dr. Sandhu was not justifiable or reasonable.

Thirteenth Defense

(Failure to Plead with Particularity)

Plaintiffs have failed to allege fraud with the particularity required by Rule 9(b) of the Federal Rules of Civil Procedure.

Fourteenth Defense

(Unenforceable Contract)

The contract or agreement alleged in the First Amended Complaint is unenforceable for the period after March 18, 2004, because it has expired.

Fifteenth Defense

(Excuse of Performance)

Defendants' alleged failure to perform alleged duties, conditions, covenants, or promises required by the contract or agreement alleged in the First Amended Complaint was excused by Dr. Sandhu's prior failure to perform his duties, conditions, covenants, or promises under the agreement.

Sixteenth Defense

(No Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction to adjudicate Plaintiffs' claims of correction of inventorship of SDGI's pending patent applications. The Court also lacks diversity jurisdiction, as there is no complete diversity of citizenship between Plaintiffs and Defendants.

Seventeenth Defense

(No Standing)

Kyphon, as merely a purported licensee of Dr. Sandhu's alleged inventions, lacks standing to sue Defendants and lacks standing to seek punitive damages.

Eighteenth Defense

(Adequate Remedy at Law)

Plaintiffs' causes of action for specific performance and prayer for injunctive relief are barred by the adequacy of Plaintiffs' remedy at law.

Nineteenth Defense

(Comparative Fault)

To the extent applicable, Defendants adopt and rely upon the doctrine of comparative fault. While denying that the incident that is the subject of this action occurred as alleged in the First Amended Complaint, in the alternative, Defendants aver affirmatively that if it is determined that fault should be assessed, the possible negligence, acts, or omissions of other persons or parties, including Plaintiffs and any of their agents in this cause, may have been a direct and proximate cause of any of the damages alleged in the First Amended Complaint. Such negligence, acts, or omissions of other person or parties, including those aforementioned, should be considered in reducing the liability of Defendants, if any, in this cause by the percentage of fault attributable to such other persons or parties in accordance with the principles enunciated in *McIntyre v. Balentine*.

Twentieth Defense

(Attorney's fees under the Consumer Protection Act)

Because Plaintiffs' claim under the Tennessee Consumer Protection Act is frivolous and without legal or factual merit, Defendants are entitled to their reasonable attorneys' fees and costs pursuant to Tenn. Code Ann. § 47-18-109(e).

Twenty-First Defense

(No Infringement)

Defendants have not infringed and do not currently infringe, either directly or indirectly, any valid claim of the '888, '404, '043, '138 or '672 patents.

Twenty-Second Defense

(Invalidity of Kyphon's Patents)

The Kyphon patents asserted against Medtronic, namely the '888, '404, '043, '138, and '672 patents are invalid because they fail to satisfy the requirements of 35 U.S.C. § 101, et seq., including, without limitation, sections 101, 102, 103, and 112.

Twenty-Third Defense

(Motion to Dismiss)

Defendants rely upon all defenses and arguments asserted in their Motions to Dismiss and supporting Memoranda.

Twenty-Fourth Defense

(Unenforceability Due to Inequitable Conduct)

The Kyphon patents asserted against Medtronic, namely the '888, '404, and '138 patents, are unenforceable due to inequitable conduct during the prosecution of those patents.

RESERVATION OF RIGHTS

Discovery in this case is ongoing, and Defendants' investigation of their defenses is continuing. Therefore, Defendants reserve the right to rely on such other additional defenses as may become available or apparent during discovery and reserve the right to supplement or amend this Answer.

MEDTRONIC'S COUNTERCLAIMS AGAINST KYPHON INC. AND HARVINDER S. SANDHU, M.D.

Defendant and Counter-Plaintiffs MSD Inc., MSD USA, and SDGI (collectively, "Medtronic") file the following counterclaims against Plaintiffs and Counter-Defendants Dr. Sandhu and Kyphon.

Parties

1. Defendant and Counter-Plaintiff MSD Inc. is a corporation organized under the laws of Indiana and has its principal place of business in Memphis, Tennessee.

2. Defendant and Counter-Plaintiff MSD USA is a corporation organized under the laws of Tennessee and has its principal place of business in Memphis, Tennessee.

3. Defendant and Counter-Plaintiff SDGI is a corporation organized under the laws of Delaware and has its principal place of business in Wilmington, Delaware.

4. On information and belief, Plaintiff and Counter-Defendant Kyphon is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1221 Crossman Avenue, Sunnyvale, California, 94089.

5. On information and belief, Plaintiff and Counter-Defendant Dr. Sandhu is a resident of New York.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, 1338, and 1367. Venue in this District is proper under 28 U.S.C. § 1391 and 1400.

Factual Background

7. The human spine consists of numerous individual bones, or vertebrae. The weight-bearing part of each vertebra is the vertebral body. Various instruments and methods

have been developed for treating compression-type bone fractures in the vertebrae and other bones.

8. One such method – known as balloon vertebroplasty – includes a procedure in which a doctor inserts a balloon into the vertebral body and inflates it with the hope of creating a cavity. The doctor then injects cement into the vertebral body to harden the structure and provide internal support for the bone. Kyphon markets a balloon-based system that is sold under the trade name "Kyphoplasty."

Medtronic's Equestra Project

9. Dr. Kevin Foley is a well-known and highly respected Memphis neurosurgeon, biomedical engineer, and inventor who has maintained a consulting relationship with Medtronic and its predecessors since 1992. In early 1999, Dr. Foley approached MSD USA and indicated that he wanted to design a mechanical device to treat vertebral compression fractures. Jeff Justis, a MSD USA engineer, began working with Dr. Foley on treatments for vertebral compression fractures.

10. In 2001, Dr. Paul Pagano an orthopedic and spine surgeon independently began developing a device to treat vertebral compression fractures.

11. In 2002, Dr. Pagano conceived of and built a prototype of his invention. Dr. Pagano was not affiliated with Medtronic when he conceived of and built his prototype device. In 2002, Dr. Pagano visited Medtronic's headquarters in Memphis, Tennessee, for the first time, and during the visit he disclosed and demonstrated the prototype of his invention. Dr. Pagano did not meet Dr. Sandhu until after he visited Medtronic's headquarters in Memphis, Tennessee in 2002.

12. After demonstrating his prototype to MSD USA personnel, Dr. Pagano joined Dr. Foley and Dr. Sandhu to work on a project developing treatments for vertebral compression fractures. MSD USA incorporated Dr. Pagano's invention and prototype into the research project.

13. Dr. Sandhu began consulting with Medtronic's predecessor Danek Medical Inc. in 1996. In 2002, MSD Inc. offered Dr. Sandhu the opportunity to join Dr. Foley and others to work on developing treatments for vertebral compression fractures. Medtronic's efforts to develop treatments for vertebral compression fractures that included Dr. Foley, Dr. Sandhu and Dr. Pagano became known within Medtronic as the "Equestra Project."

14. From 2002 through 2005, Dr. Sandhu provided consulting services to MSD USA in connection with the Equestra Project. While working on the Equestra project, Dr. Sandhu used his invention by discussing the ideas embodied in his Disclosure with Medtronic consultants and employees, and advocated using these ideas to improve the Medtronic device that was the subject of the Equestra project.

15. Because of his consulting duties with MSD USA, Dr. Sandhu traveled frequently to Memphis. During this time period, Dr. Sandhu had access to and gained substantial confidential information regarding the Equestra Project, including the specific uses of the project, the status and direction of the project, and the particular configuration of the Equestra devices. Dr. Sandhu was intimately involved in the Equestra Project.

16. Among other things, Dr. Sandhu participated in a meeting with MSD USA consultants and employees where the strategy for developing the Equestra Project was discussed and refined and prototype devices were examined. Dr. Sandhu participated in laboratory testing where prototype Equestra devices were tested on cadavers and refined. Throughout his

involvement with the Equestra Project, Dr. Sandhu specifically understood that information regarding the Equestra Project, including the existence of the Equestra Project, was strictly confidential and was a trade secret.

Dr. Sandhu's Agreements with Medtronic

17. Dr. Sandhu signed a series of agreements with MSD USA, MSD Inc., and their predecessors, beginning with a Confidentiality Agreement that was effective January 2, 1996. Dr. Sandhu's other agreements with MSD USA, MSD Inc., and their predecessors include a Consulting Agreement that was effective March 1, 1998, a Mutual Confidentiality Agreement that was effective on March 18, 1999; a Confidentiality Agreement that Dr. Sandhu signed on January 22, 2000; and a Consulting Agreement that Dr. Sandhu signed on March 16, 2001.

18. On April 26, 2002, Dr. Sandhu signed a Consulting Agreement with MSD USA (the "2002 Agreement"). Under the 2002 Agreement, Dr. Sandhu agreed to provide consulting services to MSD USA related to the development and marketing of products used in spinal surgery and treatment of spinal disorders.

19. Pursuant to the express terms of the 2002 Agreement, Dr. Sandhu also agreed to (1) keep confidential all "material, information, data and devices developed in the course of performing the activities described in the Agreement"; and (2) "assign" to MSD USA "any ideas, inventions, improvements or suggestions" arising from the performance of his duties under the 2002 Agreement.

20. Under the terms of the 2002 Agreement, Dr. Sandhu also agreed to assign to MSD USA his ideas or inventions related to his duties and activities under the 2002 Agreement.

21. On May 25, 2003, before the term of the 2002 Agreement had expired, Dr. Sandhu signed an agreement entitled "Exclusive Personal Services Agreement" (the "2003

Agreement"). Under the 2003 Agreement, Dr. Sandhu agreed to provide services to MSD USA related to the development and marketing of products and services used in spinal surgery and the treatment of spinal disorders.

22. Under paragraph 7.5 of the 2003 Agreement, Dr. Sandhu "acknowledge[d] that [he] will be given access to substantial and significant Confidential Information and trade secrets of MSD USA in order to allow [him] to perform the Services."

23. Under paragraph 4.1 of the 2003 Agreement, any information acquired by Dr. Sandhu from MSD USA, including any material, information, data, and devices developed in the course of performance of the agreement, were to be maintained in confidence and not disclosed to any third party without first obtaining the prior written consent of MSD USA.

24. Pursuant to Sections 2 and 4 of the 2003 Agreement, Dr. Sandhu's non-disclosure obligations under the 2003 Agreement remain in effect.

25. Dr. Sandhu further agreed that for one year after the termination of the agreement he would not "serve as a researcher, investigator, consultant or employee of or in any other way render services to or for the benefit of, any third party regarding any of the areas involved in the Agreement ..."

26. Under the terms of the 2003 Agreement, Dr. Sandhu also agreed to assign to MSD USA his ideas or inventions related to the development and marketing of products used in spinal surgery and the treatment of spinal disorders.

Kyphon Induces Dr. Sandhu to Breach his Agreements with MSD USA and Disclose Confidential Information

27. On information and belief, Kyphon learned about the Equestra Project and the advantages it would have over Kyphon's balloon tamps from Dr. Sandhu and then embarked on a course of conduct designed to try to obstruct the Equestra product launch and try to keep MSD

USA's device off the market. Kyphon agreed to pay Dr. Sandhu $20 million dollars to induce him to breach his agreements and duties to MSD USA.

28. Shortly after inducing Dr. Sandhu to breach his agreements, Kyphon issued a January 2006 press release and claimed that it had entered into an "exclusive consulting relationship" with Dr. Sandhu and had agreed to pay him $20 million dollars to consult with Kyphon regarding "minimally invasive spine diagnosis and therapy" and to provide Kyphon with an "exclusive license" to his "invention" related to treatment of "vertebral compression fractures." But in January 2006, Dr. Sandhu (1) was still bound by certain terms of his contracts with MSD USA; (2) had already assigned, or agreed to assign, to MSD USA his ideas or inventions related to the development and marketing of products used in spinal surgery and treatment; and (3) his contract with MSD USA expressly prohibited him from consulting with competitors like Kyphon in the area of spinal disorders.

29. Dr. Sandhu breached terms of the 2003 Agreement with MSD USA by entering into a consulting agreement with Kyphon while still bound by his "Exclusive Personal Services Agreement" with MSD USA, and by refusing to assign his contributions to the Equestra project to Medtronic as required by the 2002 and 2003 Agreements.

30. Dr. Sandhu also breached his agreements with MSD USA by disclosing to Kyphon confidential information referred to in paragraphs 21-28 of the Original Complaint. In particular, Dr. Sandhu has disclosed to Kyphon, among other things, MSD USA's development of a provisional device undergoing further refinement, the particular configuration of the product, Dr. Sandhu's attendance at the MERI Lab at which a vertebral facture reduction device was tested, and the existence and specific contents of a draft brochure for the Equestra Project.

First Counterclaim by MSD USA

(Dr. Sandhu's Breach of Express and Implied Agreements)

31. Counter-Plaintiff reasserts and incorporates by reference the allegations set forth in paragraphs 1-30 as though fully set forth herein.

32. Dr. Sandhu signed written agreements with MSD USA, including the 2002 Agreement and 2003 Agreement, wherein Dr. Sandhu agreed to provide consultant services to MSD USA related to the development and marketing of products and services used in spinal surgery and the treatment of spinal disorders. The 2003 Agreement prohibits Dr. Sandhu from serving as a researcher, investigator, consultant, or employee for the benefit of, or from rendering services to, anyone developing a similar or competing product until after April 30, 2006.

33. When Dr. Sandhu was providing consulting services to MSD USA he had access to and knowledge of MSD USA's proprietary and confidential information and trade secrets. The 2002 and 2003 Agreements prohibit Dr. Sandhu from disclosing MSD USA's confidential information and trade secrets to any third party without first obtaining the prior written consent of MSD USA. Sandhu has not sought, and MSD USA has not given, any such consent.

34. Dr. Sandhu had an express agreement and a common law duty to maintain the confidentiality of MSD USA's proprietary and confidential information and trade secrets.

35. Dr. Sandhu has entered into an agreement with Kyphon under which he has been or will be paid $20 million by Kyphon. On information and belief, Dr. Sandhu has been working with and providing consulting services to Kyphon since at least November 2005 related to the development of products used in spinal surgery and the treatment of spinal disorders.

36. Dr. Sandhu has breached the 2003 Agreement by providing consulting services to Kyphon.

37. Dr. Sandhu has breached the 2002 and 2003 Agreements by refusing to assign his contributions to the Equestra Project to Medtronic.

38. Dr. Sandhu has also breached the terms of the 2002 and 2003 Agreements by disclosing MSD USA's proprietary and confidential information and trade secrets to Kyphon.

39. As a direct and proximate result of Dr. Sandhu's actions and breaches of his express and implied agreements with MSD USA, MSD USA continues to suffer damage.

Second Counterclaim by MSD USA

(Kyphon's Interference with Existing or Prospective Business Relationship)

40. MSD USA reasserts and incorporates by reference the allegations set forth in paragraphs 1-39.

41. MSD USA had an existing or prospective business relationship with Dr. Sandhu.

42. Kyphon had knowledge of MSD USA's existing or prospective business relationship with Dr. Sandhu.

43. Having an improper motive or using improper means, Kyphon intended to cause the breach of, termination of, or interference with the existing or prospective business relationship between MSD USA and Dr. Sandhu.

44. MSD USA has been damaged by Kyphon's tortious interference and continues to suffer damage.

Third Counterclaim by MSD USA

(Kyphon's Inducement to Breach Express and Implied Agreements)

45. MSD USA reasserts and incorporates by reference the allegations set forth in paragraphs 1-44 as though fully set forth herein.

46. Upon information and belief, Kyphon became aware of Dr. Sandhu's agreements with MSD USA, intended to induce Dr. Sandhu's breach of the agreements, and acted with

malice toward that end. Dr. Sandhu did in fact breach his agreements, and Dr. Sandhu would not have breached his agreements absent Kyphon's conduct.

47. Kyphon's actions constitute an inducement of Dr. Sandhu to breach his express and implied agreements with MSD USA, under Tennessee common law as well as Tennessee statutory provisions, including Tenn. Code Ann. § 47-50-109.

48. As a result of Kyphon's wrongful conduct, MSD USA has suffered and will continue to suffer damage.

Fourth Counterclaim by MSD USA

(Kyphon and Dr. Sandhu's Misappropriation of Trade Secrets)

49. MSD USA reasserts and incorporates by reference the allegations set forth in paragraphs 1-48 as though fully set forth herein.

50. MSD USA's trade secrets include unpatented information regarding the development and marketing of products and services used in spinal surgery and the treatment of spinal disorders (the "Trade Secrets"). These constitute trade secrets under Tenn. Code Ann. Section 47-25-1701 *et seq.*, and derive independent economic value from not being generally known to the public or to MSD USA's competitors, who could benefit economically from disclosure or use of MSD USA's Trade Secrets.

51. Such Trade Secrets were developed and maintained at the cost of significant research, expense, and time, resulting in a significant competitive advantage to MSD USA in the marketplace.

52. MSD USA took reasonable steps to maintain the secrecy of its Trade Secrets, and its Trade Secrets were kept confidential and not generally known to others prior to Kyphon and Dr. Sandhu's misappropriation of these Trade Secrets.

53. Kyphon and Dr. Sandhu, either directly or through their agents, used improper means to misappropriate MSD USA's Trade Secrets and used them without authorization.

54. At the time MSD USA's Trade Secrets were misappropriated, Kyphon and Dr. Sandhu knew that the Trade Secrets were in fact trade secrets, and were owned and protected by MSD USA. Kyphon acquired these Trade Secrets improperly through Dr. Sandhu, who had a duty to maintain the confidentiality of MSD USA's Trade Secrets.

55. In a January 17, 2006, press release, Kyphon stated that Dr. Sandhu's "expertise" would be "of significant value to Kyphon in the development of technologically advanced products and procedures," indicating that Kyphon plans to commercialize the information that it obtained from Dr. Sandhu.

56. As a direct and proximate result of Kyphon's and Dr. Sandhu's above described acts and omissions, MSD USA has suffered and will continue to suffer harm.

57. MSD USA is also entitled to recover from Kyphon and Dr. Sandhu all wrongfully-earned profits and other benefits received by Kyphon and Dr. Sandhu.

58. Kyphon and Dr. Sandhu have acted intentionally, willfully, and maliciously, and in conscious disregard of MSD USA's rights and interests, and with the purpose of injuring MSD USA and depriving it of its rights. As a result, MSD USA is entitled to an award of punitive damages.

Fifth Counterclaim by MSD USA

(Declaratory Judgment)

59. MSD USA reasserts and incorporates by reference the allegations set forth in paragraphs 1-58 as though fully set forth herein.

60. Pursuant to T.C.A. § 29-14-101, *et seq.*, MSD USA requests a declaratory judgment against Kyphon and Dr. Sandhu.

61. Dr. Sandhu provided consulting services to MSD USA in connection with the Equestra Project under the 2002 and 2003 Agreements. Pursuant to the express terms of those agreements, Dr. Sandhu assigned to MSD USA all rights, title, and interest in the work he performed on the project and the ideas that he developed related to the project.

62. Because Kyphon and Dr. Sandhu are claiming ownership of the rights that Dr. Sandhu transferred to MSD USA, there is a real and justiciable controversy regarding MSD USA's ownership of these rights.

63. MSD USA seeks a declaration that MSD USA owns all of the rights, title, and interest in the intellectual property that forms the basis of the Equestra Project, the Arcuate XP and related products and devices developed by MSD USA.

Sixth Counterclaim by MSD USA

(Injunction)

64. MSD USA reasserts and incorporates by reference the allegations set forth in paragraphs 1-63 as though fully set forth herein.

65. Through the conduct described above, Kyphon has and continues to interfere with MSD USA's contractual rights by possessing and using MSD USA's confidential information and Trade Secrets. These actions have and will cause immediate and irreparable harm to MSD USA that may not be compensable by money damages.

66. MSD USA requests that this Court issue a preliminary as well as permanent injunction, enjoining Kyphon from interfering with MSD USA's relationship and agreements with Dr. Sandhu, and enjoining Kyphon and Dr. Sandhu from using any of MSD USA's confidential information and Trade Secrets.

Seventh Counterclaim by MSD Inc., MSD USA, and SDGI

(Declaratory Judgment of Unenforceability Due to Inequitable Conduct)

67. MSD Inc., MSD USA, and SDGI reassert and incorporate by reference the allegations set forth in paragraphs 1-66 as though fully set forth herein.

68. This Counterclaim is an action for declaratory judgment pursuant to 28 U.S.C. §§ 2201 et seq.

69. Kyphon filed suit against Medtronic and alleged in its Complaint that MSD Inc., MSD USA, and SDGI infringe United States Patent Nos. 4,969,888 ("the '888 patent"), 5,108,404 ("the '404 patent"), 6,235,043 ("the '043 patent"), 6,440,138 ("the '138 patent") and 6,863,672 ("the '672 patent"). MSD Inc., MSD USA, and SDGI now seek a declaration of unenforceability due to inequitable conduct as to the '888, '404, and '138 patents, and any applications or patents related thereto.

United States Patent Application Serial No. 07/308,724 (the "'724 application")

70. The '724 application was filed on February 9, 1989. The '724 application was pending at the United States Patent and Trademark Office (the "PTO") until its issuance, as the '888 patent, on November 13, 1990. The named inventors on the '724 application are Arie Scholten and Mark A. Reiley, and the prosecuting attorneys were the law firm of Townsend and Townsend. During the entirety of the time that the '724 application was pending before the PTO, all those substantively involved with the prosecution of the '724 application had a duty to disclose to the PTO information material to the patentability of one or more claims of the application.

71. In the background section of the '724 application, the applicants stated that the only methods of treatment for vertebral compression fractures were bed rest and aspirin:

> Osteoporotic vertebral body compression fractures are currently treated with bed rest, analgesics, and intravenous hydration during the first week after onset of the problem. These steps are followed by the prescription of a soft or firm spinal corset, depending upon the physician's preference. In most cases, the corset is not worn because the patient suffers much discomfort and oftentimes greater discomfort than that due to the fracture of the vertebral body. The fracture pain lasts from two to eight months. In many cases, patients with osteoporotic vertebral body collapse fractures require about one week in an acute care hospital and two to three weeks in an extended care facility until they are able to move about independently and with only moderate pain. Current treatment does not substantially alter the conditions of the vertebral body.

See Prosecution History for the '724 Application filed on February 9, 1989 at Pg. 1, line 23 – Pg. 2, line 4. The applicants made this representation to the PTO despite having specific knowledge of other, more advanced medical procedures for the treatment of vertebral compression fractures.

72. Specifically, the applicants were aware, prior to filing the '724 application that a medical procedure known as vertebroplasty was being performed as a method of treatment of vertebral fractures. Vertebroplasty is a percutaneous procedure for fixation of vertebral fractures by the introduction of a bone filler, such as bone cement, by use of a needle. This procedure reads on elements of one or more of the claims of the '724 application.

73. One or more of the inventors, and/or others substantively involved with the filing and prosecution of the '724 application, failed to disclose the inventors' knowledge of vertebroplasty to the PTO for consideration in the '724 patent application. Moreover, the inventors and/or others substantively involved with the filing and prosecution of the '724 application intentionally misrepresented the state of the prior art to the PTO. Vertebroplasty is material prior art to the claims of the '724 patent. In doing the aforesaid acts, one or more of the inventors, and/or others substantively involved with the filing and prosecution of the '724 application, violated the duty of disclosure and duty of candor, and did so with the intent to

deceive the PTO as evidenced by the fact that those with a duty to disclose knew of the existence of this highly material art, yet failed to disclose it to the PTO and intentionally misrepresented the state of the art. This misrepresentation and failure to disclose material art renders the claims of the '888 patent, and all patents and patent applications related to the '724 application, unenforceable.

United States Patent Application Serial No. 07/567,862 (the "'862 application")

74. The '862 application was filed on August 15, 1990. The '862 application was pending at the PTO until its issuance, as the '404 patent, on April 28, 1992. The named inventors on the '862 application are Arie Scholten and Mark A. Reiley, and the prosecuting attorneys were the law firm of Townsend and Townsend. During the entirety of the time that the '862 application was pending before the PTO, all those substantively involved with the prosecution of the '862 application had a duty to disclose to the PTO information material to the patentability of one or more claims of the application.

75. In the background section of the '862 application, the applicants stated that the only methods of treatment for vertebral compression fractures were bed rest and aspirin:

> Osteoporotic vertebral body compression fractures are currently treated with bed rest, analgesics, and intravenous hydration during the first week after onset of the problem. These steps are followed by the prescription of a soft or firm spinal corset, depending upon the physician's preference. In most cases, the corset is not worn because the patient suffers much discomfort and oftentimes greater discomfort than that due to the fracture of the vertebral body. The fracture pain lasts from two to eight months. In many cases, patients with osteoporotic vertebral body collapse fractures require about one week in an acute care hospital and two to three weeks in an extended care facility until they are able to move about independently and with only moderate pain. Current treatment does not substantially alter the conditions of the vertebral body.

See Prosecution History for the '862 Application filed on August 15, 1990, at Pg. 1, line 29 – Pg. 2, line 9. The applicants made this representation to the PTO despite having specific knowledge of other, more advanced medical procedures for the treatment of vertebral compression fractures.

76. Specifically, the applicants were aware, prior to filing the '862 application that a medical procedure known as vertebroplasty was being performed as a method of treatment of vertebral fractures. Vertebroplasty is a procedure fixing vertebral fractures by the introduction of a bone filler such as bone cement. The procedure reads on elements of one or more of the claims in the '862 application.

77. One or more of the inventors, and/or others substantively involved with the filing and prosecution of the '862 application failed to disclose the inventors' knowledge of vertebroplasty to the PTO for consideration in the '862 patent application. Moreover, the inventors and/or others substantively involved with the filing and prosecution of the '862 application intentionally misrepresented the state of the prior art to the PTO. In doing the aforesaid acts, one or more of the inventors, and/or others substantively involved with the filing and prosecution of the '862 application violated the duty of disclosure and duty of candor, and did so with the intent to deceive the PTO as evidenced by the fact that those with a duty to disclose knew of the existence of this highly material art, yet failed to disclose it to the PTO and intentionally misrepresented the state of the art. This misrepresentation and failure to disclose material art renders the claims of the '404 patent, and all patents and patent applications related to the '862 application, unenforceable.

United States Patent Application Serial No. 09/055,805 (the "'805 application")

78. The '805 application was filed on April 6, 1998. The '805 application was pending before the PTO until its issuance as the '138 patent on August 27, 2002, assigned to Kyphon, Inc. The named inventors on the '805 application are Mark A. Reiley and Arie Scholten, and the prosecuting attorney was Daniel Ryan of the law firm Ryan Kromholz and Manion. During the entirety of the time that the '805 application was pending before the PTO, all those substantively involved with the prosecution of the '805 application had a duty to disclose to the PTO information material to the patentability of one or more claims of the application.

79. On October 20, 2000, prosecuting attorney Daniel Ryan filed a patent application on behalf of Mark A. Reiley. That application was identified as Application No. 09/693,272 and ultimately issued on August 26, 2003, as U.S. Patent No. 6,610,091 ("the '091 patent"). The '091 patent was directed to devices and surgical methods to treat various types of adult spinal pathologies.

80. On March 5, 2002, during the prosecution of the '091 patent and while the '805 application was pending, prosecuting attorney Daniel Ryan submitted to the PTO on behalf of Mark A. Reiley, an Information Disclosure Statement citing, inter alia, U.S. Patent No. 5,015,255 to Kuslich ("the Kuslich patent"). The Kuslich patent is prima facie prior art as to the claims of the '805 application. The Kuslich patent describes all of the elements of one or more claims of the '805 application and constitutes prior art, as it was issued on May 14, 1991. As such, the Kuslich patent was material to the prosecution of the '805 application.

81. One or more of the inventors, and/or others substantively involved with the filing and prosecution of the '805 application failed to disclose the Kuslich patent to the PTO for

consideration in the '805 patent application. In doing the aforesaid act, one or more of the inventors, and/or others associated with the filing and prosecution of the '805 application violated the duty of disclosure and duty of candor, and did so with the intent to deceive the PTO as evidenced by the fact that those with a duty to disclose knew of the existence of this highly material art, yet failed to disclose it to the PTO. This failure to disclose material prior art, renders the claims of the '138 patent, and all patents and patent applications related to the '805 application, unenforceable.

Eighth Counterclaim by MSD Inc., MSD USA, and SDGI

(Declaratory Judgment of Non-Infringement and Invalidity of the Kyphon Patents)

82. MSD Inc., MSD USA, and SDGI reassert and incorporate by reference the allegations set forth in paragraphs 1-83 as though fully set forth herein.

83. The manufacture, use, sale, offer to sell, and/or importation of the Arcuate XP does not infringe and has not infringed any valid claim of Kyphon's '888, '404, '138, '672, or '043 patents. Medtronic, its customers, and all others have the right to manufacture, have made, use, sell, offer to sell, and import the Arcuate XP, unhampered and unrestricted by Counter Defendant Kyphon.

84. The claims of Kyphon's '888, '404, '138, '672, and '043 patents are invalid for failure to comply with one or more provisions of the Patent Laws of the United States, Title 35, United States Code, §§ 101 et seq., including without limitation Sections 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Defendants and Counter-Plaintiffs MSD Inc., MSD USA, and SDGI request that the Court enter judgment:

(a) Dismissing the First Amended Complaint against Defendants in its entirety with prejudice;

(b) Finding that all relief requested in the First Amended Complaint be denied with prejudice;

(c) Declaring that Medtronic's Arcuate XP does not infringe and has not infringed any of the claims of the Kyphon Patents under any subsection of 35 U.S.C. § 271;

(d) Declaring that the Kyphon Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112;

(e) Declaring that MSD USA owns all of the rights, title and interest in the intellectual property that forms the basis of the Arcuate XP and related products and devices developed by MSD USA and its consultants;

(f) Enjoining Kyphon from using any of MSD USA's confidential information or Trade Secrets that it obtained from Dr. Sandhu;

(g) Enjoining Dr. Sandhu from further disclosing or using any confidential information or Trade Secrets that he obtained from MSD USA;

(h) Awarding Medtronic compensatory damages, including any benefits wrongfully received or retained by Dr. Sandhu or Kyphon;

(i) Awarding Medtronic punitive and exemplary damages, including the trebling of the actual damages;

(j) Awarding Defendants and Counter Plaintiff Medtronic their costs of this action and reasonable attorneys' fees to the extent permitted by law; and

(k) Granting such other and further relief to which Defendants and Counter Plaintiff Medtronic are justly entitled.

DEMAND FOR JURY TRIAL

Medtronic demands a trial by jury on all issues where a jury trial is permitted by law.

Dated: April 12, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of April, 2007, a copy of the foregoing electronically filed document was served on the parties listed below via first class mail, postage prepaid, unless said party is a registered CM/ECF participant who has consented to electronic notice, and the Notice of Electronic Filing indicates that Notice was electronically mailed to said party:

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